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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,711	06/30/2000	Guy Serre	045636-5037	8393

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EXAMINER	
COOK, LISA V	
ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/582,711	SERRE ET AL.	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-7 and 9-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-7 and 9-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicants response to the non-Final Office Action mailed 14 June 2004 is acknowledged. In amendment filed therein Claim 11 was modified. New claims 16-18 were added.

Telephonic Interview

2. Examiner phone attorney Sally Teng (34,297) on 28 January 28, 2005 regarding the allowance of claim 19 and any claims configured to depend therefrom. Applicant's representative declined the modification. Accordingly the following action was prepared.

NEW GROUNDS OF REJECTION NECESSITATED BY AMENDMENT

Claim Objections

3. Claim 17 is objected to because of the following informalities: X2 is Ser or Pro; *any*. It appears that "any" is a typo and should be "and". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 16-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 16-18 are drawn to peptide compositions, wherein the motif X0-X1-Ser-Cit-His-X2-X3 includes instances where X0, X1, X2, or X3 **can be any residue**.

However, the specification does not teach such embodiments. For example see page 6 lines 1-6. Accordingly, the claims are new matter. Applicant is invited to show support for the claims in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 3, 5, 7, and 9-18 (previously claims 1, 3, 5, 7, and 9-15) are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for sequences consisting of sequences 7, 8, and 9, it does not reasonably provide enablement for any and all peptide constructs comprising the three amino acid motif Ser-Cit-His, wherein said motif is an epitope recognized by an auto-antibody. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to utilize the invention commensurate in scope with these claims.

The instant invention is directed to an isolated peptide comprising the motif Ser-Cit-His. Therefore the claims read on any and all polypeptides, which would include Ser-Cit-His for antibody binding. In other words, the claimed invention reads on any and all peptides comprising Ser-Cit-His irrespective of the amino acids flanking the motif. The prior art teaches that the residues flanking the amino acid motif regulate antibody recognition or binding. The flanking residues may impose conformational constraints upon the presentation of the epitope for antibody binding.

Further variability maybe seen when the motifs are repeated or housed in larger sequences. This is supported by the reference of Briggs et al. (European Journal of Cancer, 1993, Vol.29A, No.2, Pages 230-237).

Only sequence identification numbers 7, 8, and 9 are exemplified in autoantibody binding or recognition. Accordingly the specification is not enabled for any and all peptides comprising Ser-Cit-His allowing for antibody binding and/or recognition.

The disclosure does not support claims directed to all possible peptide constructs, which would read on the instant claims, or specifically comprising the motif Ser-Cit-His. Accordingly the claims are not commensurate in scope with any and all peptide molecules comprising Ser-Cit-His as recited in claims 1, 3, 5, 7, and 9-18.

The language of claims 1, 3, 5, 7, and 9-18 are directed to peptides comprising the motif Ser-Cit-His however only sequence identification numbers 7, 8, and 9 are demonstrated in the instant application.

Thomas E. Creighton, in his book, "Proteins: Structures and Molecular Properties, 1984, (pages 314-315) teaches that variation of the primary structure of a protein can result in an instable molecule. He also teaches a single amino acid change can cause a mutant.

With the exception of SEQ ID NO:7, 8, and 9, the skilled artisan cannot envision the detailed structure of the encompassed compositions and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation.

There is no guidance in the specification as to how to determine which sequences including the Ser-Cit-His motif other that sequences 7, 8, or 9; would allow for autoantibody binding or recognition. It appears that undue experimentation would be required of one skilled in the art to practice the instant claimed invention using the teachings of the specification. See Ex parte Forman, 230 USPQ 546 BPAI, 1986.

In absence of guidance and/or working examples, one skilled in the art would reasonably conclude that a large number of peptide constricts comprising the Ser-Cit-His would be considered in order to practice the invention. The scope of the claims must bear a reasonable correlation with the scope of enablement. One skilled in the art would be forced into undue experimentation in order to practice the broadly claimed invention.

Response to Arguments

6. Applicants contend that the structural and functional limitations sufficiently narrow the scope of the claimed Ser-Cit-His containing peptides. Therefore the claims do not read on any peptide comprising the Ser-Cit-His sequences but must encompass peptides that contain an epiotope recognized by anti-filaggrin. This argument was carefully considered but not found persuasive because it has been held that the recitation that an element performs a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

A recitation of the intended utility into the preamble of a compound claim which can otherwise stand alone is not considered a further limitation of the claim. *In re Ridden*, 318 F.2d 761, 138 USPQ 112, *In re Maeder*, 337 F.2d 875, 143 USPQ 248.

Applicant argues that it is within the skill of the artisan to obtain peptides having the structural motif Ser-Cit-His, since peptide synthesis is routinely performed by the skilled artisan. This argument was carefully considered but not found persuasive because the specification must teach how to make and use the invention, not teach how to figure out for oneself how to make and use the invention. *In re Gardner*, 166 U.S.P.Q. 138 (CCPA 1970).

Applicant contends that the generation of Ser-Cit-His sequences that bind anti-filaggrin autoantibodies is undue experimentation because the antigen/antibody art is well known and the relative level of skill in this art is quite high. Examiner agrees that antigen/antibody interaction is well known, however the instant claims are directed to the physiological binding activity of Ser-Cit-His and anti-filaggrin autoantibodies, which is not well known.

Enablement for a single compound cannot provide enablement for the breath of claims sought in arts, which are unpredictable. *Ex parte Hitzeman*, 9 USPQ2d 1821 (BPAI 1987). A single embodiment may provide broad enablement in cases involving predicatable factors, but more is required in cases involving unpredictable factors, such as chemical or physiological activity. *In re Shokal*, 242 F.2d 771, 113 USPQ 283, 285 (CCPA 1957)(a single species is seldom, if ever, sufficient to support a generic claim); *In re Langer*, 503 F.2d 1380, 183 USPQ 288 (CCPA 1974)(proff of utility for the preferred species does not necessarily establish the utility of the remaining members of the genus); *Ex parte Lanham*, 135 USQ 106 (POBA 1961)(biological activity of chemicals is notoriously unpredictable).

Applicant argues that the claims do not encompass inoperative peptides because only peptides that meet the recited structural and functional limitations are encompassed in the claims.

Further the skilled artisan would readily recognize inoperative embodiments and not seek out embodiments that do not work. This argument was carefully considered but not found persuasive because the functional limitations are not given patentable weight and the determination of inoperative embodiments is not deemed undue as exhibited by the cited prior art. Thomas E. Creighton, in his book, "Proteins: Structures and Molecular Properties, 1984, (pages 314-315) teaches that variation of the primary structure of a protein can result in an instable molecule. He also teaches a single amino acid change can cause a mutant.

The prior art teaches that the residues flanking the amino acid motif regulate antibody recognition or binding. The flanking residues may impose conformational constraints upon the presentation of the epitope for antibody binding.

Further variability maybe seen when the motifs are repeated or housed in larger sequences. This is supported by the reference of Briggs et al. (European Journal of Cancer, 1993, Vol.29A, No.2, Pages 230-237). Accordingly the rejection is maintained.

Allowable Subject Matter

7. Claim 19 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. For reasons aforementioned, no claims are allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see httpr//pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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